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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,699	11/17/2003	Timothy J. Cunningham	53844-5021	5388

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,699	CUNNINGHAM ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 11/02/07 has been entered.

2. The rejection of claims 1-2 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn due to the amendment of the claims.

3. The rejection of claims 1-3 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 & 7 of U.S. Patent No. 6,262,024 is withdrawn due to the amendment of the claims to closed language, in which a 9 amino acid peptide is not reasonably obvious over that previously patented.

4. The rejection of claims 1-3 & 22 under 35 U.S.C. 102(b) as being anticipated by Cunningham et al. (IDS Ref # C; 2000) is withdrawn due to the amendment of the claims to closed language.

5. Applicant's arguments filed 11/02/07 have been fully considered but they are not deemed to be persuasive.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-3 & 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In contrast to Applicants' assertions on page 3 of the response, no proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application exists for the new recitation of "said variant comprising between 1-9 conservative amino acid substitutions of SEQ ID NO: 1, and said variant including SEQ ID NO: 2". In contrast, pages 12 -13 of the specification do not describe the peptide of SEQ ID NO: 2 as a conservatively substituted variant of the peptide of SEQ ID NO: 1; nor does such reasonably flow from the description on pages 12-13 of the specification for what constitutes a conservatively substituted variant peptide thereof. For example, although amino acid residues # 1, 4, 6 & 9 are identical between SEQ ID NOs: 1 & 2, Ala at position # 2 of SEQ ID NO: 2 is not an aromatic or basic/positively charged amino acid residue like His in SEQ ID NO: 1; His at position # 3 of SEQ ID NO: 2 is not an acidic/negatively charged amino acid residue like Glu; Gln at position # 5 is not a neutral hydrophilic amino acid residue like Ser; Glu at position # 7 is not a hydrophobic amino acid residue like Ala; Ser at position # 8 is not a basic amino acid residue like Gln.

Therefore, the amended claims clearly constitute new matter based on Applicants' own definition of what constitutes "a conservative amino acid substitution" on pages 12-13 of the specification.

8. Claims 1-3 & 22 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 20070726, and as follows. This is a written description rejection.

As previously made of record, the specification fails to describe what critical amino acids are reasonably correlated to any activity. In contrast to Applicants' assertions on page 4 of the specification, no where in the specification is it described which of the 9 amino acid residues in SEQ ID NO: 1 or which of the different 9 amino acid residues in SEQ ID NO: 2 are directly responsible for either "phospholipase activity" (which is not claimed), or responsible for any "neuron-survival-promoting" activity, where no specific population of neurons with their own unique compliment of receptor molecules are described, or recited in the claims. In other words, no generic survival promoting peptide is known in the art, or reasonably described within the instant specification for any variant peptide molecule. Therefore, as previously made of record, one skilled in the art cannot reasonably visualize or predict what critical amino acid residues would structurally characterize the genus of polypeptides encompassed by claims 1-2, especially based on the comparison of SEQ ID NO: 1 with SEQ ID NO: 2, and that claimed, where all 9 amino acid residues of SEQ ID NO: 1 are claimed to be changeable. Therefore, as previously

made of record, the claims still currently represent an invitation for others to discover a representative number of species with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, because not a single amino acid residue position is critical, by definition, since all 9 amino acids residues are claimed as capable of being conservatively substituted.

Analogous to the situation decided in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), "an adequate written description of a DNA [product] requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA [product] itself". *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) held that claims directed to mammalian FGFs were found unpatentable due to lack of written description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only the originally claimed "synthetic" peptide species of SEQ ID NO: 1, and nonelected peptide species of SEQ ID NO: 2, have been described in the instant specification.

Accordingly, the court held in *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) that:

"One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is".

and that:

"A description of a genus of cDNAs [products] may be achieved by means of a recitation of a representative number of cDNAs [products], *defined by nucleotide sequence*, failing in the scope of the genus or of a recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus* [emphasis added]. This is analogous to enablement of a genus under 112, [first paragraph], by showing the enablement of a

representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218".

Therefore, Applicants are clearly not in possession of the claimed genus of peptides, and for the reasons previously made of record. See again MPEP 2163. Thus, Applicants' arguments are not persuasive, for the reasons made of record.

9. Claims 1-3 & 22 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated peptide consisting of SEQ ID NO: 1, or for kits comprising such a peptide, does not reasonably provide enablement for any structurally and functionally undefined "CHEC-9 peptide", or "variant thereof', or for kits "for treating an [undefined] neurodegenerative disorder". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper No: 20070726, and as follows.

Similar to that previously made of record, the name, "conservative variant thereof", alone (e.g., as defined on pages 12-13 & 17-19 of the specification) provides little structural and functional characterization for knowing how to make and use the instant invention. The specification still fails to define what specific amino acids are critical for making a functional CHEC-9-related variant peptide, or what specific amino acid residues distinguish the CHEC-9 peptide of the instant invention from any different CHEC-9-related protein without the desired activity of the instant invention. It is noted that no properly executed IDS nor copies of the Westley or Cunningham references listed on page 6 of the response have further been made of record for the Examiner's consideration.

The Cunningham Declaration under 37 CFR 1.132 filed 11/2/07 is insufficient to overcome the rejection of the claims as set forth in the last Office action because:

First, evidence related to an animal model of MS is not on point with the rejection of record, because MS is not described within the specification as "a neurodegenerative disorder or inflammatory disorder" to be treated. In contrast, page 13 of the specification merely mentions various autoimmune diseases…including MS… the context of which is not readily apparent, as it relates to that claimed. In addition, autoimmune diseases are not reasonably equivalent to a "disorder with an inflammatory component", etc.; nor are they described within the instant specification as such. Alternatively, ALS is described as a disorder to be treated by the instant invention (e.g., pg. 7 of the specification). However, ALS is not reasonably representative of all "neurodegenerative disorders or inflammatory disorders", nor would one skilled in the art reasonably extrapolate ALS as being such, without requiring undue experimentation to determine otherwise; consistent with the teachings of Jackowski previously made of record.

Second, although transient "phospholipase A2 inhibitory activity" is an interesting observation by Applicants, Figure 3 of the declaration clearly shows that this result is not significant before 10 days "post immunization" and after 15 days "post immunization". Page 6 of the specification then states that "[w]hile sPLA2 enzymes have long been targeted for anti-inflammatory therapies, *inhibitors have had little clinical success* [emphasis added]".

Lastly and more importantly, the claims are directed toward a "neuron survival-promoting activity", not "phospholipase A2 inhibitory activity", in which the claims fail to identify a single population of neurons where any "survival-promoting" activity works. Because each population of neurons possess their own unique compliment of receptor molecules, and

because not a single neuron is disclosed in the specification, or known in the art, as possessing a receptor for CHEC-9 or any putative "conservative amino acid" "variant thereof" receptor, the specification clearly fails to provide sufficient guidance for one of ordinary skill in the art to know how to make and use the currently claimed invention without requiring undue experimentation to determine such, for the reasons previously made of record, and as illustrated by the teachings of Rudinger and Jackowski previously made of record.

10. Claims 1-3 & 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "said variant comprising between 1-9 conservative amino acid substitutions of SEQ ID NO: 1, and said variant including SEQ ID NO: 2" makes little sense, because base claim 1 recites "consisting of" and therefore, no more than 9 substitutions can be permitted, yet SEQ ID NO: 2 is 9 amino acids long with 4 amino acids identical between SEQ ID NO: 2 and SEQ ID NO: 1. Therefore, it is confusing how 9 conservative substitutions are possible. Likewise, because none of the remaining 5 amino acids of SEQ ID NO: 2 are conservative substitutions of SEQ ID NO: 1, how can 1-9 substitutions be made and still "include" SEQ ID NO: 2 (see *pp* # 7 above).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert C. Hayes, Ph.D./
Primary Examiner, Art Unit 1649
April 2, 2008